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APPLICATION NO.	FĮLĨNG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,668	12/18/2001	Stephen Griffin	1001.1535101	6574
28075	7590 . 12/02/2003	EXAMINER		
CROMPTON, SEAGER & TUFTE, LLC			FOREMAN, JONATHAN M	
1221 NICOLLET AVENUE SUITE 800		ART UNIT	PAPER NUMBER	
MINNEAPOLIS, MN 55403-2420			3736	
		DATE MAILED: 12/02/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)			
Office Action Summary		10/025,668	GRIFFIN ET AL.			
		Examiner	Art Unit			
		Jonathan ML Foreman	3736			
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sheet with the	correspondence address			
THE I - Externance - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be ly within the statutory minimum of thirty (30) d will apply and will expire SIX (6) MONTHS fro e, cause the application to become ABANDON	timely filed lays will be considered timely. om the mailing date of this communication. NED (35 U.S.C. § 133).			
3 tatus 1)⊠	Responsive to communication(s) filed on 04	Sentember 2003				
·		his action is non-final.				
2a)⊠	,		procedution as to the marite is			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims						
•		n				
• "	Claim(s) <u>1-35</u> is/are pending in the applicatio					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
	\ \ \ \ <del></del>					
•	☑ Claim(s) <u>1-35</u> is/are rejected.					
7) 🗀	<del></del>					
8)(8	Claim(s) are subject to restriction and/o	or election requirement.				
• •	ion Papers The appellication is objected to by the Evamin	or				
,	The specification is objected to by the Examino The drawing(s) filed on is/are: a)☐ acce		vaminer			
10)						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
•						
Priority under 35 U.S.C. §§ 119 and 120  13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
a)	1. Certified copies of the priority documen	its have been received				
			ation No			
	<ul><li>2. Certified copies of the priority document</li><li>3. Copies of the certified copies of the priority</li></ul>					
* (	application from the International B See the attached detailed Office action for a lis	ureau (PCT Rule 17.2(a)).				
14) 🔲 /	Acknowledgment is made of a claim for domes	tic priority under 35 U.S.C. § 11	9(e) (to a provisional application).			
	a)  The translation of the foreign language processes The translation of the foreign language processes. The translation is made of a claim for domestic the content of the translation is a claim for domestic the content of the translation is a claim for domestic the content of the translation is a claim for domestic the content of the					
Attachmer	•	, .				
1)  Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 Notice of Inform	nary (PTO-413) Paper No(s) al Patent Application (PTO-152)			
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#### **DETAILED ACTION**

# Information Disclosure Statement

The information disclosure statement filed 12/16/02 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1, 2, 17 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,662,621 to Lafontaine.

In reverence to claims 1, 2, 20 and 21, Lafontaine discloses applicant's claimed invention including a stainless steel metal elongate core wire (24) having an elastic limit (Col. 5, line 64 - 66); and a polymer jacket (22; Col. 5, lines 24 - 26) surrounding a distal portion of the core wire having an elastic limit, the jacket being more stiff than the distal portion of the core wire which it surrounds so that when deformed into a shape within the elastic limit of the metal and beyond the elastic limit of the polymer, the tip retains the shape in that once the polymer jacket acquires its stiff, memory retention shape, the core wire has the shape provided by the jacket (Col. 5, lines 46 - 59).

In reference to claims 17 - 19, Lafontaine discloses applicant's claimed method including deforming the polymer jacket and the core wire into a shape; heating the deformed polymer jacket to a temperature at or above the glass transition temperature of the shape memory polymer (Col. 5, lines 49 - 56); and cooling the deformed jacket to a temperature below the glass transition

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temperature of the shape memory polymer to maintain the shape (Col. 5, lines 56 - 59). Lafontaine discloses reheating and cooling the jacket to form and maintain different shapes including the original shape (Col. 7, lines 24 - 34).

### Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 3, 4, 22 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,662,621 to Lafontaine in view of U.S. Patent No. 5,772,609 to Nguyen et al.

In reference to claims 3, 4, 22 and 23, Lafontaine discloses the elongate core wire comprising a metal (Col. 5, line 64 – 66), but fails to disclose the metal being a super elastic metal comprising a nickel titanium alloy. Nguyen et al. teaches forming the elongate core wire of either stainless steel or a super elastic metal comprising a nickel titanium alloy (Col. 4, lines 44 – 48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the metal of the elongate core wire as disclosed by Lafontaine to include a super elastic metal comprising a nickel titanium alloy as taught by Nguyen et al. in that Nguyen et al. teaches the two metals forming the elongate core wire to be interchangeable (Col. 4, liens 44 – 48). Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, modifying the elongate core wire as disclosed by Lafontaine to be formed of a super elastic metal comprising a nickel titanium alloy is a design consideration within the skill of the art.

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Claims 5 – 16 and 24 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5. U.S. Patent No. 5,662,621 to Lafontaine in view of U.S. Patent No. 6,485,458 to Takahashi. In reference to claims 5 - 16 and 24 - 35, Lafontaine discloses a shape memory polymer surrounding a portion of the core wire, but fails to disclose the polymer being polyurethane, polynorbornene, polcaprolactone, polymethylmethacylate, PLLA, PLLA OGA, PL/D LA, PMMA, polyethylene, polyisoprene, styrene-butadiene or photocrosslinkable polymer. However, Takahashi discloses a shape memory polymer surrounding a core wire wherein the polymer consists of poluorbornen, styrene-butadiene, polyurethane, polyisoprene, polyester, polyolefin, acrylic and styrene-acrylic (Col. 5, lines 56 - 67). Takahashi teaches that other shape-memory materials can be used in addition to those disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made use any shape memory polymer as taught by Takahashi in the device as disclosed by Lafontaine in that Takahashi teaches that shape memory polymers are interchangeable. Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, replacing the shape memory polymer as disclosed by Lafontaine with any other shape memory polymer is a design consideration within the skill of the art.

# Response to Arguments

6. Applicant's arguments filed 9/4/03 have been fully considered but they are not persuasive. Applicant has asserted that Lafontaine fails to disclose any structure of a guidewire and a polymer jacket being stiffer than the portion of the core wire it surrounds. However the examiner disagrees. In regards to claims 1 and 20, the term guidewire is only found in the preamble and is given no patentable weight. Additionally, the elongate metal core (24) as disclosed by Lafontaine is a

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guidewire in that it is used to guide a catheter. The polymer jacket (22) that surrounds the core wire is at times stiffer than the core wire it surrounds. Lafontaine discloses the core wire having elastomer joints (Col. 6, lines 10 - 13). Lafontaine discloses the polymer jacket (22) being softened in a heated state and easily deflectable. But once the jacket is cooled it returns to its pre-shaped, relatively stiff, memory retention state (Col. 5, lines 54 - 59). Once in this stiff state, the core wire can be removed allowing the jacket to retain its shape (Col. 6, line 65 - Col. 7, line 39). If the core were stiffer than the jacket, then the core would not be able to be removed alone leaving the jacket in place.

#### Conclusion

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization

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where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

**JMLF** 

December 1, 2003

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700